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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/600,773	06/20/2003	Martin Grunwald	100727-50/Heracus 402-KGB	6455
27384 7590 08/31/2007 NORRIS, MCLAUGHLIN & MARCUS, PA 875 THIRD AVENUE 18TH FLOOR NEW YORK, NY 10022			EXAMINER JASTRZAB, KRISANNE MARIE	
			ART UNIT 1744	PAPER NUMBER
			MAIL DATE 08/31/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/600,773

Applicant(s)

GRUNWALD ET AL.

Examiner

Krisanne Jastrzab

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 June 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 and 16-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 and 16-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The dependent claims refer to "the impression materials and/or their components", which is found to lack proper antecedent basis because independent claim 1 requires "two-component impression materials". The recitation of "and/or their components" is vague and indefinite. Clarification is required.

With respect to claim 6, the recitation of "an addition cross-linking silicon impression material is used" is unclear because it is unknown what is required by "is used". This statement is found to be vague and indefinite.

With respect to claim 7, "wherein polymers are used" is also found to be vague and indefinite because it is unclear as to what the polymers are "used" for. Clarification is required.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-4, 8-9, 11-12 and 17-18 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Larson U.S. patent No. 5,540,876.

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Larson teaches substantially the invention as claimed, namely the radiation sterilization of polymeric impression material for dental impressions. It is taught the the polymer can be a blend and include polysiloxanes, and that the material can be treated while pre-packaged, with gamma radiation to achieve sterilization. See column 1, lines 5-15, column 2, lines 25-45 and 60-68 and column 3, lines 15-30, column 7, Example 12, and column 9, lines 25-29.

Claims 1-5, 8-9, 11-12 and 17-18 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Olsen U.S. patent No. 4,952,618.

Olsen teaches gamma sterilization of an elastomeric polymer for medical use applications wherein the polymer composition can include polyacrylates and alginate and is preferably sterilized with gamma radiation between 2.5 and 4 Mrads. The polymer can be formed by blending two powder components. Also, the patent teaches sterilizing the polymers with their backing materials as a system. See the abstract, column 2, lines 20-25, column 3, lines 15-35, column 4, lines 2-3 and lines 19-35, column 6, lines 63-68 and columns 7 and 8, lines 1-10 of each.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over either Larson or Olsen as applied to claim 1 above.

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Both references teach sterilization of the polymer material in a packaged state ready for medical use and it would have been obvious to one of ordinary skill in the art to include any components required for application of the polymer within the same package because the efficacy of gamma sterilization of packaged articles for a myriad of uses is well recognized and conventional in the art.

Claims 6-7 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over either Larson or Olsen as applied to claim 1 above, and further in view of Amos U.S. patent No. 5,804,620.

Amos teaches that it is known in the art to include polysiloxanes as an additive in polymers used for medical applications which will be sterilized with gamma radiation because such siloxanes enhance the integrity of the polymers following radiation treatment. Amos teaches the presence of polysiloxanes in an amount around 3% with greater amounts also taught as effective. See the abstract, column 1, lines 10-23, column 2, lines 8-25, column 3, lines 18-27, column 4, lines 14-26, column 5, lines 1-20 and the claims.

It would have been obvious to one of ordinary skill in the art to include polysiloxanes in the polymers of either Larson or Olsen for the recognized purpose of enhancing the integrity of those polymers following sterilization with gamma radiation.

Response to Arguments

Applicant's arguments filed 6/14/2007 have been fully considered but they are not persuasive.

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Applicant argues that neither Larson or Olsen anticipate the claimed invention because they do not teach elastomeric materials. The Examiner would first point out that claim 1 does not require elastomeric materials. Secondly, and most importantly, the Examiner would disagree with Applicant's allegation that Larson and Olsen do not teach elastomeric materials and would maintain that the thermoplastic materials taught by Larson and those in Olsen are, in fact, elastomeric. See the attached definition of "elastomer" from The Condensed Chemical Dictionary. Please note that both Larson and Olsen teach several of the elastomers listed in the definition.

Applicant further argues that Larson does not anticipate the claimed invention because Larson does not irradiate a two-component material, however, the Examiner would disagree and point Applicant to Example 9 of Larson which irradiates a polymer made of two components including transpolyisoprene and silicon dioxide, and Example 10 which irradiates a blend of transpolyisoprene and rubber. Larson clearly teaches gamma irradiation of multi-component polymers.

Applicant also argues that Olsen fails to teach a two-component impression materials, however, the Examiner could continue to maintain that the material taught in Olsen, including an elastomer and a hydrocolloid such as alginate, clearly meet this limitation. See again column 3, lines 9-36, column 4, lines 1-3 and the examples.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Krisanne Jastrzab whose telephone number is 571-272-1279. The examiner can normally be reached on Mon.-Thurs. 6:00am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gladys Corcoran can be reached on 571-272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Krisanne Jastrzab/
Primary Examiner
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August 27, 2007